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GROUP 1600

DATE: August 12, 2002**Application No.: 08/286,189****Our Ref: 1038-384 MIS:jb**

TO:	FAX #	PHONE #
Examiner: Jeffrey S. Parkin Group/Art Unit: 1648 US Patent Office	(703) 308-4242	(703) 308-2227

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CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8)Applicant(s) **Sonia E. Sanhueza**

Docket No.

1038-384 MIS:jb

Serial No

08/286,189

Filing Date

August 5, 1994

Examiner

Jeffrey S. Parkin

Group Art Unit

1648Invention **INACTIVATED RESPIRATORY SYNCYTIAL VIRAL VACCINES****FAX RECEIVED****AUG 13 2002****GROUP 1600****OFFICIAL**I hereby certify that this _____ Reply Brief _____

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	Filing Date	August 5, 1994	
	First Named	Sonia E. Sazubueza	
	Group Art Unit	1648	
	Examiner Name	Jeffrey S. Parkin	
Total Number of Pages in This Submission	10	Attorney Docket Number	1038-384 MIS

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Michael J. Stewart (Reg. No. 24,973)
Signature	
Date	August 12, 2002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : 08/286,189
Appl'n. No. : Sonia E. Sanhueza
Filed : August 5, 1994
Title : INACTIVATED RESPIRATORY SYNCYTIAL VIRAL VACCINES
Grp./A.U. : 1648
Examiner : Jeffrey S. Parkin
Docket No. : 1038-384 MIS:jb
Date : August 12, 2002

#36
Reply Brief
8/13/02

BY FACSIMILE

The Commissioner of Patents
and Trademarks,
Box AF
Washington, D.C. 20231,
U.S.A.

REPLY BRIEF

(Response Under 37 CFR 1.116 - Expedited Procedure)

Dear Sir:

This Reply Brief is submitted in triplicate in response to the Examiner's Answer dated June 10, 2002 and to the Advisory Action of the same date.

In the Advisory Action, the Examiner indicated that the Declaration of Gregory A. Prince had not been considered on the basis of lack of timely submission and the absence of good and sufficient reasons why the Declaration had not been earlier presented.

An issue in this appeal is the extent to which the cotton rat is an art-recognized model of vaccine efficacy in humans. It is the foundation of the Examiner's argument that the pending claims are rejected under 35 USC 112, first paragraph, as lacking an enabling disclosure, that the cotton rat is not such a model.

Applicants had previously provided attorney argument, backed by reference to the literature, in support of their assertion that the cotton rat is an art-recognized model, in the reasonable belief that such argument would be persuasive

without further proof. When such argument was rejected, it was considered that a Declaration by a recognized expert in the field (see the CV attached to the Declaration), namely Professor Gregory A. Prince, would assist the Board in realizing the correctness of the applicants argument and that the appealed claims are fully enabled and fully comply with 35 USC 112, first paragraph.

The Declaration was not submitted earlier, since it was not considered necessary until the receipt of the Examiner's Final Rejection that such a Declaration would be necessary.

In addition, the Examiner specifically invited applicants to submit further evidence, stating in the Final Action:

"Applicants are advised that the presentation of more appropriate publication or other evidence providing reproducible data derived from the cotton rat model might obviate the rejection." (emphasis added)

As pointed out in the Appeal Brief, the Prince Declaration was submitted specifically in response to this Invitation.

It is submitted that the Declaration of Gregory A. Prince should be entered and considered in this Appeal.

As to the Examiner's indications of the uncertainties in the art, in the Prince Declaration, it is pointed out that, on the strength of cotton rat data, the NIH funded a clinical trial of RSV prophylaxis in high risk infants using immunoglobulin (Prince, para. 4.2). This trial confirmed what the cotton rat had shown that immunoglobulin reduced viral titers (Prince, para. 4.3).

As set forth in the Appeal Brief, applicants determined that, if respiratory syncytial virus is first purified and then inactivated using β -propiolactone, ascorbic acid or octyl glycopyranoside, then a safe and effective vaccine preparation can be obtained which, in particular, elicits a protective immune response without causing enhanced pulmonary pathology.


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Applicants present independent claim 1 to the vaccine, independent claims 5, 12 and 14 directed to the method of preparation and independent claim 15 to a method of immunizing.

With respect to the product claims, it is noted that the vaccine not only may be used in the method of claim 15, but also may be used in diagnostic procedures (see original claims 17 to 19; Application No. 08/472,174). It is submitted that the product claims are fully enabled on this basis, irrespective of the cotton rat model issue.

With respect to the method claims, it is submitted that the method steps defined are fully described and exemplified in the disclosure. It is submitted that the method claims are fully enabled on this basis, irrespective of the cotton rat model issue.

Respectfully submitted,



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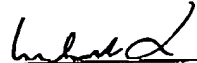
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